

**REMARKS**

Applicants express gratitude to the Examiner for the telephonic interview on September 14, 2010.

Applicants respectfully request reconsideration and withdrawal of the outstanding Office Action rejections in view of the foregoing amendments and following remarks. Claims 39-41 and 43-47 have been amended and claim 48 has been added. No new matter has been added.

Interview Summary

During a September 14, 2010 telephonic interview with the Examiner, Applicants' representative proposed claim amendments to overcome the outstanding rejections. Applicants' representative proposed limiting claim 39 to treatment of tuberculosis and adding a new method claim directed to a "method of eliciting an immune response to a disease state which is now or later may be in a mammal...." The Examiner stated that the proposed claim amendments appeared to adequately address the outstanding issues pending further consideration. The Examiner also mentioned that he would reconsider the term "or an immunogenic fragment thereof" in the claims.

Response to rejections under 35 U.S.C. § 112

Claims 39-47 remained rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the term "treating" denotes that the administered component alters the disease state favorably for the host, while polypeptides that elicit an immune response to a disease state may

or may not treat a host exhibiting the disease state. Thus, the Examiner asserts that the description of methods of eliciting an immune response to a disease state in the specification does not support actually treating the disease state.

Applicants submit that claim 39 has been amended to limit the disease state to tuberculosis. The specification provides a written description of experimental evidence demonstrating treatment of tuberculosis in mice and guinea pigs in the Examples described on pages 11 and 12. Claim 40 further limits claim 39 by specifically reciting *Mycobacterium* antigens to be used as the polypeptide domain. Applicants further submit that thousands of patents reciting claims directed to methods comprising administering immunogenic fragments of antibodies/polypeptides have been issued in the U.S. and that it is well known that immunogenic fragments are effectively used in vaccines. Accordingly, Applicants submit that claims 39 and 40 satisfy the written description requirement and respectfully request that the rejection be withdrawn.

New claim 48 has been added, which is directed to a "method of eliciting an immune response to a disease state which is now or later may be in a mammal..." Applicants submit that written description support for this new claim can be found throughout the specification, e.g., page 3, second full paragraph, page 5, first and second full paragraphs, page 7, fourth paragraph, page 8, third paragraph, and the Examples. Claims 41-47 have been amended to depend from claim 48. the specification provides written description support for eliciting an immune response to a number of disease states in a mammal depending on the particular polypeptide that is administered. Thus, Applicants submit that the rejection of claims 41-47 has been

rendered moot as the claims are no longer directed to a "method of treatment."  
Accordingly, Applicants respectfully request that the rejection of claims 41-47 be  
withdrawn.

### Conclusions

In view of the foregoing amendment and remarks presented herein, all of the  
stated grounds of objection and rejection have been properly traversed, accommodated,  
or rendered moot. Applicant therefore respectfully requests that the Examiner  
withdrawn the outstanding rejections. Early and favorable action is awaited.

If the Examiner believes that personal communication will expedite prosecution  
of this application, the Examiner is invited to telephone the undersigned at the number  
provided.

The Commissioner is hereby authorized to charge any fees and to credit any  
overpayments that may be required with respect to this paper to Counsel's Deposit  
Account No.02-2135.

Respectfully submitted,

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